

DEPARTMENT OF VETERANS AFFAIRS
Justification and Approval
For
Other Than Full and Open Competition

1. **Contracting Activity:** Department of Veterans Affairs, VISN 16, Oklahoma City (635) Medical Center. 2237 # 635-14-1-224-0338.
2. **Nature and/or Description of the Action Being Processed:** This is for the purchase of Sovaldi 400mg tablets, this is a new medication used to treat Hepatitis C. Hepatitis C is on the leading causes of liver cancer and liver transplant in the United States. This is a new firm-fixed-price contract, the product cannot be purchased directly from the manufacturer (Gilead Sciences), and it is only available from Pharmaceutical Wholesalers.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** We currently have 4 patients on the liver transplant list, it is imperative we start these patients on this medication immediately. If these patient can begin the therapy immediately it is possible there condition may improve enough for them to not to require a liver transplant. The cost and necessity has been discussed with the Chief of Staff who agrees with the urgency. Because of the overwhelming circumstances and the possibility of death for the patients if they do not start this medication immediately we consider this an emergency situation. Sovaldi is \$1000 per tablet; it is sold by the bottle, 28 tablets per bottle. Therapy is 3 months; we will purchase 12 bottles so there will be no disruption in therapy for the 4 patient to receive the medication.
4. **Statutory Authority Permitting Other than Full and Open Competition:**
 - (X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
 - (X) (2) Unusual and Compelling Urgency per FAR 6.302-2;
 - () (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
 - () (4) International Agreement per FAR 6.302-4
 - () (5) Authorized or Required by Statute FAR 6.302-5;
 - () (6) National Security per FAR 6.302-6;
 - () (7) Public Interest per FAR 6.302-7;
5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):** McKesson is our primary Pharmaceutical prime vendor, we have accounts setup with them and have confirmed they have the product in stock and can provide next day delivery. Because time is critical in this scenario, we request McKesson be used. Accordingly, McKesson Corporation is the only firm capable of providing the supplies and services described in Section III above without the Veteran's Health Administration experiencing unacceptable delays in fulfilling its requirements. We currently have 4 patients on the liver transplant list, it is imperative we start these patients on this medication immediately. If these patient can begin the therapy immediately it is possible there condition may improve enough for them to not to require a liver transplant. The cost and necessity has been discussed with the Chief of Staff who agrees with the urgency. Because of the overwhelming circumstances and the possibility of death for the patients if they do not start this medication immediately we consider this an emergency situation.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** McKesson Corporation is the only firm capable of providing the supplies and services described in Section III above without the Veteran's Health Administration experiencing unacceptable delays in fulfilling its requirements.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** Currently there is no government contract in place for this medication, the current price is \$1000.00 per tablet from the pharmaceutical wholesalers I have contacted (McKesson and ASD).
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Due to the emergent situation and the limited availability of the medication market research was limited to 1. Not available for direct purchase from the manufacturer, 2. Pharmaceutical wholesaler McKesson and ASD had the medication listed at the same price.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** There is only one manufacturer of this medication; they will not sell the product directly to individual facilities. The medication is distributed only through pharmaceutical prime vendors, I have called two of the pharmaceutical prime vendors and both sell the product at the same price. McKesson is the Federal pharmaceutical prime vendor and has the product available.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:**
See Section VI above.
11. **A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:**
Government contracting office in the process of negotiating a contract with Gilead Sciences for Sovaldi.
12. **Requirements Certification:** I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.
(This signature is the requestor's supervisor, fund control point official, chief of service, someone with responsibility and accountability)

 D Ph.

(Insert Name)

Title Pharmacy Procurement Supervisor

Facility VA OGC Pharmacy 119
635

12-16-2013

Date

13. **Approvals in accordance with FAR 6.304** This part is filled out by Contracting Staff as part of the Justification

- a. **Contracting Officer's Certification (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

(Insert Name)

Date

Title

Facility

- b. **P&C:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

(Insert name)

Date

CHIEF, PURCHASING AND CONTRACTING

(OFFICE LOCATION/Facility) Network Contracting Office 16

The Chief is last signature required below \$150K; delete this note and and the information below: If between \$150k and \$650K, add NCM signature block and delete this note

- c. **NCM/PCM (Required \$3K and above):** I certify the justification meets requirements for other than full and open competition.

Aaron Villalpando

Date

Network Contract Manager

Network Contracting Office 16

Add the next 2 signatures if above \$650K; then delete this note

- d. **SAO (If over 650K):** I certify the justification meets requirements for other than full and open competition.

Ricky L. Lemmon

Date

SAO Director, Central Region

- e. **VHA HCA Review and Approval:** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and recommend approval (if over \$12.5 million) or approve (\$650K to 12.5 million) for other than full and open competition.

Mr. Norbert Doyle

Date

Chief Procurement Officer

VHA, Head of Contracting Activity

Add the below signature block if greater than \$12.5M; delete this note

- f. **VA Deputy Senior Procurement Executive Approval (over \$12.5 million but not exceeding \$50 million):** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for other than full and open competition.

C. FORD HEARD
Deputy Senior Procurement Executive (DSPE)
Office of Acquisition and Logistics
Department of Veterans Affairs

Date

Add the below signature block if greater than \$50M; delete this note

- g. **VHA Senior Procurement Executive Approval (over \$50 million):** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for other than full and open competition.

Jan R. Frye
Deputy Assistant Secretary for Acquisition and Logistics
Senior Procurement Executive (SPE)
Department of Veterans Affairs

Date